

## Article - Health - General

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§2–801.

- (a) In this subtitle the following words have the meanings indicated.
- (b) (1) “Essential off–patent or generic drug” means any prescription drug:
  - (i) For which all exclusive marketing rights, if any, granted under the Federal Food, Drug, and Cosmetic Act, § 351 of the federal Public Health Service Act, and federal patent law have expired;
  - (ii) 1. That appears on the Model List of Essential Medicines most recently adopted by the World Health Organization; or  
2. That has been designated by the Secretary as an essential medicine due to its efficacy in treating a life–threatening health condition or a chronic health condition that substantially impairs an individual’s ability to engage in activities of daily living;
  - (iii) That is actively manufactured and marketed for sale in the United States by three or fewer manufacturers; and
  - (iv) That is made available for sale in the State.
- (2) “Essential off–patent or generic drug” includes any drug–device combination product used for the delivery of a drug for which all exclusive marketing rights, if any, granted under the Federal Food, Drug, and Cosmetic Act, § 351 of the federal Public Health Service Act, and federal patent law have expired.
- (c) “Price gouging” means an unconscionable increase in the price of a prescription drug.
- (d) “State health plan” has the meaning stated in § 2–601 of this title.
- (e) “State health program” has the meaning stated in § 2–601 of this title.
- (f) “Unconscionable increase” means an increase in the price of a prescription drug that:

(1) Is excessive and not justified by the cost of producing the drug or the cost of appropriate expansion of access to the drug to promote public health; and

(2) Results in consumers for whom the drug has been prescribed having no meaningful choice about whether to purchase the drug at an excessive price because of:

(i) The importance of the drug to their health; and

(ii) Insufficient competition in the market for the drug.

(g) “Wholesale acquisition cost” has the meaning stated in 42 U.S.C. § 1395w-3a.

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